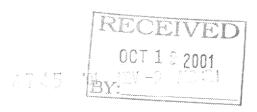


October 17, 2001



James E. Hoadley, PhD
Nutrition Labeling & Programs Team
Division of Nutrition Science & Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington DC 20204

RE:

Docket 01Q-0313; Health Claim Petition

To Expand Oats Soluble Fiber and CHD Claim

Dear Dr. Hoadley:

Please note the enclosed supplemental information, dated September 7, 2001, regarding the above referenced health claim petition for Oatrim (BetaTrimTM) submitted by the Quaker Oats Company and Rhodia Inc. as petitioners.

This supplemental information responds to your request for additional details regarding the Gallaher Intestinal Contents Supernatant Viscosity Methodology contained in the petition specifically identified as "Study 1 & 2". Under the 1st tab you will note the complete studies described by Dr. Gallaher, dated January 14, 1999. Under the 2nd tab, you will note Study 3 explaining some of the results and additional information from Dr. Gallaher regarding his methodology.

I believe this responds to your request. If you have further questions regarding this matter, please call me at 609-860-4653.

Singerely.

James T. Elfstrum

Manager, Regulatory Affairs

JTE/jn:01-156

Enclosure

cc:

Priscilla Samuel

Mark L. McGowan

010-03/3

SUP 1

DATE:

September 7, 2001

OFFICE OF NUTRITION PRODUCTS, LABELING AND DIETARY SUPPLEMENTS
CENTER FOR FOOD SAFETY & APPLIED NUTRITION FOOD AND DRUG ADMINISTRATION
200 C STREET SW
WASHINGTON, DC 20204

PETITIONERS: The Quaker Oats Company

617 W. Main Street Barrington, IL 60010

&

Rhodia Inc.

CN 7500, 259 Prospect Plains Road

Cranbury, NJ 08512-7500

SUBJECT:

OATRIM (BETATRIM™) HEALTH CLAIM

PETITION

Petition to Expand the Oats Soluble Fiber and Coronary Heart Disease Health Claim, (21 CFR

101.81)

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